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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-240-4500
FAX: 504-240-4566

November 9, 1999

WARNING LETTER NO. 2000-NOL-03

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Hung V. Huynh, Vice-President
Captain Henry Seafood, Inc.
725 Milwhite Road
Empire, Louisiana 70050

Dear Mr. Huynh:

On June 21, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your shrimp dock, located at 725 Milwhite Road, Empire, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations*, (CFR) Part 123, and the Current Good Manufacturing Practice (CGMP) regulations for foods, Title 21, CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your product, fresh shrimp, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventative system of food safety controls known as Hazard Analysis Critical Control Points (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrate to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the June 21, 1999, inspection, the FDA investigator observed shortcomings in your system that were identical to those pointed out in the April 9, 1998, inspection and stated in the untitled letter sent to your firm on May 29, 1998. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the Form FDA 483, which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The observation of concern to us is as follows:

- You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for fresh shrimp to control the food safety hazard of undeclared sulfites.

  Based on the information you provided our investigator, only some of your incoming shrimp contain sulfites. In this case, receipt is a critical control point (CCP) and it will be necessary for your firm to ascertain which incoming lots contain sulfites and which do not. Likewise, labeling/invoicing is a CCP because you must provide the buyer with information regarding which lots contain sulfites and which do not. Your plan must also provide for monitoring, record keeping and verification at these CCPs [21 CFR 123.6(c)].

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable condition is corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problem.

The above identification of the violation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations. You should take prompt action to correct this deviation. Failure to promptly correct the deviation may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection, you made a verbal commitment to correct the observed deficiency. Our investigator documented this commitment by annotation of the Form FDA 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violation, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to the U.S. Food and Drug Administration, Attention: Ms. Patricia K. Schafer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127, telephone number (504) 240-4519. Should you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer.

Sincerely,

James E. Gamet
District Director
New Orleans District